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Examiner: Catherine S. Williams
Group Art Unit: 3763

STATUS OF CLAIMS

Claims 1-28 are presently pending.

Claims 4 and 18-28 are withdrawn as belonging to a non-elected species.

Claims 1-3 and 5-17 are currently pending and under examination.

REMARKS

Rejection of the claims under 35 U.S.C. § 102(e)

Claims 1-2, 5-8, 10 and 13-17 are presently rejected under 35 U.S.C. § 102(e) as anticipated by Trerotola (U.S. App. No. 2005/0055012).

In the Office Action, the Examiner relies upon Trerotola as disclosing a "multilumen hemodialysis catheter that includes two active lumens (36, 38) within an outer wall of a portion of a catheter at least partially surrounding a false lumen (32) within the outer wall. See figure 3A and paragraph 0029 for closed slit valve 50. The false lumen contains an aqueous solution. See paragraph 0009."

Applicant respectfully traverses the rejection and asserts that the invention as claimed is not anticipated by the teachings of Trerotola. Trerotola does not teach all of the elements of Applicant's claimed invention, which is directed to a medical device with anti-microbial properties comprising a catheter having a portion that is partially insertable into the body of a patient and accessible from outside the body once the portion is inserted, wherein the portion has an outer wall, at least one active lumen within the outer wall, and a false lumen within the outer wall, and wherein the false lumen has a distal portion and a proximal portion, the false lumen contains an anti-microbial agent that provides the outer wall with anti-microbial properties, the distal portion of the false lumen is sealed, and the at least one active lumen at least partially surrounds the false lumen.

Trerotola does not teach a "false lumen," as claimed by Applicant in independent claim 1. As defined by Applicant, a false lumen is a "lumen which is not used in the main function of the catheter but which for a separate secondary function. In particular the false lumen 40 is used to deliver the anti-microbial agents to the device. In addition, the false lumen 40 does not have

an opening at the end of the distal portion 44." (see specification on page 5, lines 20-26). Trerotola does not teach a false lumen.

Rather, Trerotola discloses "[a] multi-lumen catheter...that permits one or more lumens to be used for acute treatments and selectively blocked when not needed, while allowing use of the other lumens to continue." Such "convertible multi-lumen catheter...comprises an elongated tube having at least two lumens and a removable obturator configured to block a lumen when it is not in use, thereby minimizing infection. The obturator may be removable so that its lumen may be used to inject fluids and the like as needed in more acute settings." (see Trerotola, paragraphs [0005]-[0006])(emphasis added).

Thus, the lumens of the catheters of Trerotola are used in the main function of the catheter and are not "false lumens" as described by Applicant. Indeed, the Examiner points to Trerotola as purportedly teaching a "false lumen (32)." However, "32" of Trerotola does not refer to a false lumen. Rather, it states that "when the guide wire 33 is removed from the catheter 34, the lumen 32 collapses and the remaining lumens 36, 38 conform to fill the dead space." (see Trerotola, paragraph [0027], the sole reference to "32")(emphasis added).

The fact that Trerotola does not teach a "false lumen" is not at all surprising, since the purpose behind the devices of Trerotola is to "keep the number of lumens in a catheter to the minimum number required for sufficient therapy. The reason for this is that as the number of lumens increases, the risk of infection increases as well...Thus, there is a need for a device which would allow for a reduction in the number of lumens once the additional lumens were no longer needed with an attendant decrease in the risk of infection long-term." (see Trerotola, paragraph [0003])(emphasis added).

Trerotola discloses two ways that this may be achieved: (1) collapsing the lumen 32 after use (see Trerotola, paragraphs [0009] and [0027]); or (2) blocking the lumen with an obturator "to prevent further usage of the blocked lumen and any further risk of infection" (see Trerotola, paragraphs [0011]-[0014])(emphasis added). In either a "collapsed" or "blocked" state, the lumen is "not in use" for any purpose (see Trerotola, paragraphs [0010]-[0011]).

Regarding claim 2, the Examiner also asserts that Trerotola discloses a "false lumen contain[ing] an aqueous solution. See paragraph 0009." Applicant respectfully states that this is a mischaracterization of the teaching of Trerotola. Paragraph [0009] of Trerotola discloses "a

first lumen adapted to insert antibiotics into a patient or for accepting a guide wire, a second lumen for inserting fluids into the patient, and a third lumen for removing fluids from the patient. The obturator may be accepted in any one or all of the lumens to selectively block the lumens as desired." Trerotola does not teach or contemplate any use of a lumen while an obturator is in place and the Examiner has provided no evidence to the contrary.

Claims 1-2, 5-6, 8-11, and 13-16 were rejected as anticipated by Bhat (USPN 6,645,135).

In the Office Action, the Examiner relies upon Bhat as disclosing a "catheter that includes at least two active lumens (90b, 92b, 94b) within an outer wall of a portion of a catheter at least partially surrounding a false lumen (14) within the outer wall. See figure 13B and 5:37-42. The false lumen contains an anti-microbial agent (radiation source) substrate (wire) or aqueous solution. See 5:48-50."

Applicant respectfully traverses the rejection and asserts that the invention as claimed is not anticipated by the teachings of Bhat. Bhat discloses an intravascular catheter having a "centerable [sic] delivery lumen for transporting a radiation source to the treatment site" (see Bhat, abstract). Bhat, however, does not disclose a false lumen, much less a false lumen where the distal portion of the false lumen is sealed. Rather, element 14 referenced by the Examiner is a "central delivery lumen 14" that is "adapted to allow the introduction of a radiation source to the treatment site" (see Bhat, col. 5, lines 27-30; see also Bhat, col. 4, lines 30-34, stating that "guidewire 16 is removed, and a radiation source is passed through delivery lumen 14 to the treatment site"). As was the case with Trerotola, there is nothing in Bhat to support the assertion that the active delivery lumen of Bhat teaches the false lumen of the present invention. The Examiner has presented no evidence to show otherwise.

In light of the above remarks, Applicant respectfully requests the Examiner to withdraw the rejection under 102(e).

Rejection of the claims under 35 U.S.C. § 103(a)

Claims 3 and 12 are presently rejected under 35 U.S.C. § 103(a) as anticipated by Trerotola in view of DiMatteo (USPN 2004/0230177). Applicant respectfully traverses the rejection and its supporting remarks.

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In the Office Action, the Examiner states that "Trerotola meets the claim limitations as described above but fails to include the anti-microbial agent bring [sic] an iodine based substance." The Examiner then relies upon DiMatteo as allegedly disclosing "an anti-infective catheter that utilizes a rod including iodine for preventing infection."

Unfortunately, even assuming that DiMatteo teaches what the Examiner purports, it does not remove the deficiencies of Trerotola. Namely, Trerotola fails to teach a false lumen, and combining the teaching of DiMatteo does not correct this basic infirmity and does not provide the missing claim elements required to make a prima facie of obviousness.

Given the above remarks, Applicant respectfully asserts that the Examiner has not shown a prima facie case of obviousness and requests that the rejection under 103(a) be withdrawn.

CONCLUSION

Applicants respectfully submit that all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite the application at large, request is made that the Examiner telephone the undersigned attorney at (908) 518-7700, ext. 7 in order to resolve any outstanding issues. The Office is authorized to charge any fees required to deposit account number 50-1047.

Respectfully submitted,

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